

III. Remarks

After entry of the amendment, claims 24-54 are pending.

Claims 1-23 have been canceled without prejudice. Claims 24-54 are supported by the originally filed claims and the specification at, for example, page 22, line 24 to page 23, line 2; and page 34, lines 1-5.

A. Rejection under 35 U.S.C. § 112

Claims 4-5, 14-15 and 21-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Upon review of the trademark database at www.uspto.gov, one skilled in the art would know that Prosolv® is the trademark for a silicified microcrystalline cellulose (Exhibit A); Expotab® is the trademark for a sodium starch glycolate (Exhibit B); and that TIMERx® is the trademark for a heteropolysaccharide and polysaccharide gum excipient (Exhibit C).

In view of the newly submitted claims, Applicants respectfully submit that the rejection is now moot.

B. Rejections under 35 U.S.C. § 102 and § 103

Claims 1-3, 6-13 and 16-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by and under 35 U.S.C. § 103 as being obvious over Gilbert et al (WO 98/40053).

In view of the newly submitted claims, Applicants respectfully submit that the rejection is moot.

C. Rejection under 35 U.S.C. § 103

Claims 4, 5, 14, 15 and 21-23 are rejected under 35 U.S.C. § 103 as being obvious over Gilbert (WO 98/40053) in combination with Baichwal et al (US Patent No. 4,994,275).

Applicants respectfully traverse the rejection and respectfully submit that the claims are unobvious over the combination of cited references and that the PTO has not established a *prima facie* case of obviousness.

The PTO asserts that any conventional controlled-release technology can be used to achieve the desired tablet formulation and admits that Gilbert does not expressly teach the TIMERx® formulation.

On May 6, 2003, a review of the patents in the PTO database from 1976 to May 6, 2003, at www.uspto.gov revealed **22,097** hits for a boolean search of "controlled," "release," and

"pharmaceutical;" **17,479** hits for a boolean search of "sustained," "release," and "pharmaceutical;" and **11,214** hits for a boolean search of "extended," "release," and "pharmaceutical."

If Gilbert teaches that any conventional controlled-release technology can be used and Gilbert does not teach TIMERx®, Applicants respectfully request to be advised why one skilled in the art would be motivated to select the Baichwal et al reference among the more than 22,000 patents from 1976 to the present in the PTO database that describe conventional controlled-release technology. Applicants respectfully submit that this rejection is improperly based on a hindsight review of the references.

Baichwal et al describe sustained release excipients. Baichwal et al do not disclose or suggest that the sustained release excipients could be used for pharmaceutical compositions comprising a combination of immediate release formulations and controlled release formulations; and does not disclose or suggest that the sustained release excipients could be used for pharmaceutical compositions where the (+) and (-) chiral enantiomers are separated in the formulation. There is simply no motivation for one skilled in the art to use the sustained release excipients described by Baichwal et al in the formulation described by Gilbert.

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

IV. Conclusion

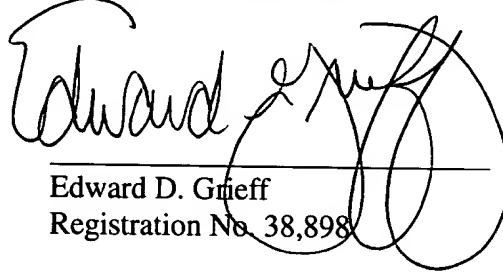
An early and favorable consideration and allowance of claims 24-54 is respectfully requested.

No fees are believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219.

The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,

HALE AND DORR LLP

A handwritten signature in black ink, appearing to read "Edward D. Grief", written over a horizontal line. The signature is stylized with large loops and a prominent "G".

Edward D. Grief
Registration No. 38,898

Date: May 8, 2003
HALE AND DORR LLP
60 State Street
Boston, MA 02109
Phone: 202-942-8400

Exhibit A



UNITED STATES PATENT AND TRADEMARK OFFICE

Trademark Electronic Search System (TESS)

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Typed Drawing

Word Mark **PROSOLV**

Goods and Services IC 001. US 001 005 006 010 026 046. G & S: Silicified microcrystalline cellulose for use in the manufacture of pharmaceutical preparations, nutritional supplements, and nutritional foodstuff preparations. FIRST USE: 19970107. FIRST USE IN COMMERCE: 19970107

IC 030. US 046. G & S: Food additives for non-nutritional purposes for use as a flavoring, ingredient or filler food. FIRST USE: 19970107. FIRST USE IN COMMERCE: 19970107

Mark Drawing Code (1) TYPED DRAWING

Serial Number 75839223

Filing Date November 3, 1999

Published for Opposition August 21, 2001

Registration Number 2505862

Registration Date November 13, 2001

Owner (REGISTRANT) PENWEST PHARMACEUTICALS CO. CORPORATION
WASHINGTON 2981 Route 22 Patterson NEW YORK 12563

Attorney of Record Michael R. Graham

Prior

Registrations 2223135;2237290
Type of Mark TRADEMARK
Register PRINCIPAL
Live/Dead Indicator LIVE

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CURR LIST	NEXT LIST	FIRST DOC	PREV DOC	NEXT DOC	LAST DOC				

Exhibit B



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Typed Drawing

Word Mark EXPLOTAB

Goods and Services IC 005. US 018. G & S: DISINTEGRATING AGENT IN COMPRESSED TABLET FORMULATIONS COMPRISING SODIUM STARCH GLYCOLATE. FIRST USE: 19710500. FIRST USE IN COMMERCE: 19710500

Mark Drawing Code (1) TYPED DRAWING

Serial Number 73068445

Filing Date November 10, 1975

Registration Number 1097160

Registration Date July 25, 1978

Owner (REGISTRANT) EDWARD MENDELL CO., INC. CORPORATION NEW YORK ROUTE 52 R.D. 5 CARMEL NEW YORK 10512

Assignment Recorded ASSIGNMENT RECORDED

Attorney of Record MICHAEL R. GRAHAM

Type of Mark TRADEMARK

Register PRINCIPAL

Affidavit Text SECT 15. SECT 8 (6-YR).

Renewal 1ST RENEWAL 19980714

Live/Dead Indicator LIVE

Exhibit C



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TIMERx

Word Mark	TIMERX
Goods and Services	IC 001. US 006. G & S: heteropolysaccharide and polysaccharide gum excipient used in the manufacture of time-release pharmaceutical preparations. FIRST USE: 19940912. FIRST USE IN COMMERCE: 19940912
Mark Drawing Code	(5) WORDS, LETTERS, AND/OR NUMBERS IN STYLIZED FORM
Serial Number	74137028
Filing Date	February 7, 1991
Filed ITU	FILED AS ITU
Published for Opposition	December 24, 1991
Registration Number	1920597
Registration Date	September 19, 1995
Owner	(REGISTRANT) EDWARD MENDELL CO., INC. CORPORATION WASHINGTON 2981 Route 22 Patterson NEW YORK 12563 (LAST LISTED OWNER) PENWEST PHARMACEUTICALS CO.

CORPORATION BY ASSIGNMENT, BY ASSIGNMENT, BY CHANGE OF
NAME WASHINGTON 2981 ROUTE 22 PATTERSON NEW YORK 12563

**Assignment
Recorded** ASSIGNMENT RECORDED
**Attorney of
Record** MICHAEL R. GRAHAM
Type of Mark TRADEMARK
Register PRINCIPAL
Affidavit Text SECT 15. SECT 8 (6-YR).
**Live/Dead
Indicator** LIVE

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